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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,079	09/20/2001	Kirk Patrick Seward	07043-091001	5103

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EXAMINER

THOMPSON, MICHAEL M

ART UNIT PAPER NUMBER

3763

DATE MAILED: 01/14/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/961,079

Applicant(s)

SEWARD ET AL.

Examiner

Michael M. Thompson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 20-23 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6, 12. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of the species election in Paper No. 16 is acknowledged. The traversal is on the ground(s) that claim 24 is generic. This is found persuasive because claim 24 appears to be generic. No other claims have been traversed as generic.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 20-23 and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4-7, 11-12, 15, 19 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards (6,009,877). Edwards teaches a method of interventional surgery comprising inserting an actuator within a body operating the actuator to cause a needle to move in a substantially perpendicular direction relative to the wall and delivering a therapeutic or

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diagnostic agent from the needle, wherein the therapeutic agent is a pharmacological agent or diagnostic (column 7).

5. Claims 6, 8, 11-12, 16-17, 19, and 24 rejected under 35 U.S.C. 102(b) as being anticipated by Barath (5,196,024). Barath teaches a method of interventional surgery comprising inserting an actuator within a body stopping adjacent a target region the actuator including an expandable section incorporating a needle and operable between an unactuated furled state and an actuated unfurled state wherein when the device is in the unfurled state the needle moves in a substantially perpendicular direction relative to the wall of the vessel, wherein the causing step includes supply an activating fluid or gas to cause expansion and deflation.

6. Claims 1-19, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Barath et al. (5,112,305). Barath teaches a method of interventional surgery comprising inserting an actuator within a body stopping adjacent a target region the actuator including an expandable section incorporating a needle and operable between an unactuated furled state and an actuated unfurled state wherein when the device is in the unfurled state the needle moves in a substantially perpendicular direction relative to the wall of the vessel, wherein the causing step includes supply an activating fluid or gas to cause expansion and deflation and delivering a therapeutic or diagnostic agent from the needle, wherein the therapeutic agent is a pharmacological agent or diagnostic. (columns 2, 3)

### *Double Patenting*

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-19 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,547,803. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the above mentioned patent and the instant application recite a method of interventional surgery comprising inserting an actuator within a body stopping adjacent a target region the actuator including an expandable section incorporating a needle and operable between an unactuated furled state and an actuated unfurled state wherein when the device is in the unfurled state the needle moves in a substantially perpendicular direction relative to the wall of the vessel, wherein the causing step includes supply an activating fluid or gas to cause expansion and deflation and delivering a therapeutic or diagnostic agent from the needle, wherein the therapeutic agent is a pharmacological agent or diagnostic.

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### Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619.

The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

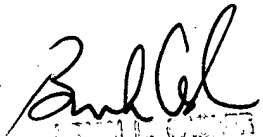
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson

Patent Examiner

MT 

January 09, 2004

  
BRIAN L. CASLER  
SENIOR PATENT EXAMINER  
TECHNICAL STAFF, GROUP 1